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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,493	01/04/2006	Philippe Chavignac	SAIME 3.3-001	8275
530 7590 12/10/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WON, BRIAN D	
			ART UNIT 4185	PAPER NUMBER
			MAIL DATE 12/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,493	Applicant(s) CHALVIGNAC, PHILIPPE	
	Examiner BRIAN WON	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>25 October 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3, 6-10, 12-14 and 16** are rejected under 35 U.S.C. 102(b) as being anticipated by **Kullik et al. (US 2003/0172930 A1)**.

Regarding claim 1, Kullik et al. discloses a device comprising:

- a source of respiratory pressurized gas (3);
- a breathing connection (2) for allowing the patient to receive pressurized gas;
- at least one sensor (10) for acquiring a parameter representative of the operation of the device;
- wherein gas source is a ventilator ([0004], lines 1-3), and ventilator is integrated into a removable module ([0014], lines 6-11) which also comprises at least one sensor (10) for acquiring a parameter representative of the operation of the device.

Regarding claim 2, Kullik et al. discloses a removable module comprising a pressure sensor (see claim 8) of respiratory gas and a flow sensor (see claim 4).

Regarding claim 3, Kullik et al. discloses a removable module fixed on the device by a removable connection such that disassembly of the module is easy ([0004], lines 1-3).

Regarding claim 6, Kullik et al. discloses a breathing connection in the form of a mask (2) ([0016], line 4).

Regarding claim 7, Kullik et al. discloses a mask not having means allowing leaks ([0009]).

Regarding claim 8, Kullik et al. discloses a removable module fixed directly on the breathing connection (Figure 1), such that the device does not comprise a conduit for conveying respiratory gas which would connect the breathing connection to a fixed offline console of the device.

Regarding claim 9, Kullik et al. discloses an ensemble formed by the breathing connection and the removable module linked to a control console (6) of the device with a link (4).

Regarding claim 10, Kullik et al. discloses a link allowing data to be transmitted between ensemble and console ([0016]).

Regarding claim 12, Kullik et al. discloses a link (4) helping to convey energy required to operate components of the removable module from console to ensemble ([0016], lines 5-7).

Regarding claim 13, Kullik et al. discloses a link (4) being a wired link (Figure 1).

Regarding claim 14, Kullik et al. discloses a ventilator being an axial ventilator ([0014], lines 11-13).

Regarding claim 16, Kullik et al. discloses in the ventilator the respective directions of the input and output of respiratory gas are substantially parallel (see Arrows in (3) in Figure 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 4-5, 15 and 17** are rejected under 35 U.S.C. 103(a) as being

unpatentable over **Kullik et al. (US 2003/0172930 A1)** in view of **Jay (US Patent 6,050,262)**.

Regarding claim 4, Kullik et al. discloses a removable connection ([0014], lines 6-11).

Kullik et al. fails to disclose a removable connection comprising a thread pitch.

However, Jay teaches a removable connection (8) (Figure 1) comprising a thread pitch (column 2, lines 46-49).

6. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with having a thread pitch taught by Jay since by doing so would produce a breathing assistance device with a module capable of being conveniently removed by unscrewing the module from the device.

Regarding claim 5, Kullik et al. discloses a removable connection ([0014], lines 6-11).

Kullik et al. fails to disclose a removable connection comprising means for clipping the removable module.

However, Jay teaches a removable connection comprising means for clipping the removable module (8) (Figure 1) ([0014], lines 6-11).

7. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with having a clipping mean taught by Jay since by doing so would produce a breathing assistance device with a module capable of being conveniently removed by unclipping the module from the device.

Regarding claim 15, Kullik et al. fails to disclose a rotor of the axial ventilator comprising a single stage.

However, Jay teaches a rotor (10) of the axial ventilator (8) comprising a single stage (Figure 1).

8. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with having a single stage rotor taught by Jay since by doing so would produce a breathing assistance device with a single stage rotor to provide user with pressurized gas.

Regarding claim 17, Kullik et al. discloses a ventilator comprising:

- a central input substantially aligned with an axis of rotation of a rotor of the ventilator (See airflow arrow in Figure 2),

Kullik et al. fails to disclose a ventilator comprising:

- an outlet allowing flux generated by rotor to be collected according to an oblique direction relative to axis of rotation, and

- means for rectifying flux that is generated and collected, so that the generated and collected flux flows out of the ventilator in a general direction substantially parallel to axis of rotation of the rotor of the ventilator.

However, Jay teaches a ventilator comprising:

- an outlet (8) allowing flux generated by rotor to be collected according to an oblique direction relative to axis of rotation (see airflow in Figure 2), and
- means for rectifying flux that is generated and collected, so that the generated and collected flux flows out of the ventilator in a general direction substantially parallel to axis of rotation of the rotor of the ventilator (see the airflow coming out of connector (6) in Figure 2).

9. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with having an outlet and means for rectifying flux taught by Jay since by doing so would produce a breathing assistance device with a ventilator capable of collecting with maximum efficiency the flux of gas pushed by the rotor

10. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kullik et al. (US 2003/0172930 A1)** in view of **Wright et al. (US 2002/0185130 A1)**.

Regarding claim 11, Kullik et al. discloses a link (4).

Kullik et al. fails to disclose the link being wireless.

However, Wright et al. teaches the link being wireless ([0029], lines 4-8).

11. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with having a wireless link taught by Wright et al. since by doing

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so would produce a breathing assistance device with a wireless link for conveniently transmitting data without using wires.

12. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kullik et al. (US 2003/0172930 A1)** in view of **Murdock et al. (US Patent 6,581,595 B1)**.

Regarding claim 18, Kullik et al. fails to disclose the device being a BPAP device.

However, Murdock et al. teaches the device being a BPAP device (Claim 12).

13. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with the device being a BPAP device since by doing so would produce a breathing assistance device operating in BPAP mode providing two levels of pressure.

Regarding claim 19, Kullik et al. fails to disclose the device being a CPAP device.

However, Murdock et al. teaches the device being a CPAP device (Claim 12).

14. It would have been obvious to one of ordinary skill in the art to modify the teaching of Kullik et al. with the device being a CPAP device since by doing so would produce a breathing assistance device operating in CPAP mode providing single level of pressure.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related

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limitations of the applicant's claimed and disclosed invention: **Kullik et al. (US 2003/0172930 A1), Jay (US Patent 6,050,262), Wright et al. (US 2002/0185130 A1) and Murdock et al. (US Patent 6,581,595 B1).** Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN WON whose telephone number is (571)270-7129. The examiner can normally be reached on Monday thru Friday, 9:00 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN WON/
Examiner, Art Unit 4185
/Terrell L McKinnon/
Supervisory Patent Examiner, Art Unit 4185

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